IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

NI-Q, LLC, Plaintiff, v. **PROLACTA BIOSCIENCE, INC.**, Defendant.	Case No. 3:17-cv-934-SI **OPINION AND ORDER**

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Michael H. Simon, District Judge.

In this patent action, Plaintiff Ni-Q, LLC ("Ni-Q") seeks a declaration that it has not infringed U.S. Patent No. 8,628,921 ("the '921 Patent") (relating to methods for testing milk from human donors). Ni-Q also seeks a declaration that the '921 Patent is invalid. Ni-Q further seeks money damages and injunctive relief under Oregon's Unlawful Trade Practices Act. By counterclaim, Defendant Prolacta Bioscience, Inc. ("Prolacta") seeks money damages and injunctive relief against Ni-Q. Prolacta alleges that the inventors of the '921 Patent have assigned their rights in that patent to Prolacta and that Ni-Q has infringed at least Claims 1, 2, and 9 of

the ’921 Patent. On June 12, 2018, the Court issued its Opinion and Order on Claim Construction. The Court adopted the parties’ stipulated construction of the term “wherein a match.” The Court also construed the disputed term “processing” in the ’921 Patent.

Before the Court is Ni-Q’s motion for partial summary judgment on two alternative grounds. First, Ni-Q argues that, based on the Court’s construction of the term “processing,” Claims 1, 2, 4, 6, 7, 8, 9, and 11 of the ’921 Patent are invalid under 35 U.S.C. § 101 for failing to claim patentable subject matter. Second, Ni-Q argues that it has not infringed any claim of the ’921 Patent because Ni-Q does not perform all of the steps required under the patent, as construed by the Court. For the reasons discussed below, Ni-Q’s motion is granted on both grounds.

STANDARDS

A. Summary Judgment

A party is entitled to summary judgment if the “movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The moving party has the burden of establishing the absence of a genuine dispute of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The court must view the evidence in the light most favorable to the non-movant and draw all reasonable inferences in the non-movant’s favor. *Clicks Billiards Inc. v. Sixshooters Inc.*, 251 F.3d 1252, 1257 (9th Cir. 2001). Although “[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge . . . ruling on a motion for summary judgment,” the “mere existence of a scintilla of evidence in support of the plaintiff’s position [is] insufficient . . . .” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 255 (1986). “Where the record taken as a whole could not lead a rational trier of fact to find for

the non-moving party, there is no genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citation and quotation marks omitted).

B. Invalidity Under 35 U.S.C. § 101

"Whether a claim is drawn to patent-eligible subject matter under § 101 is a threshold inquiry" and "an issue of law." *In re Bilski*, 545 F.3d 943, 950-51 (Fed. Cir. 2008). Section 101 provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." "The [Supreme] Court has long held that this provision contains an important implicit exception. '[L]aws of nature, natural phenomena, and abstract ideas' are not patentable." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012) (first alteration added, second alteration in original) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

There is two-step test to determine patent eligibility under § 101. The first step is to determine whether the claims are directed to a patent-ineligible subject matter, such as a naturally occurring phenomenon. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014). The second step is to "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 566 U.S. at 78). An "inventive concept" is "an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" *Id.* (alteration in original) (quoting *Mayo*, 566 U.S. at 72-73).

C. Infringement

An infringement analysis also involves a two-step process. *Phil-Insul Corp. v. Airlite Plastics Co.*, 854 F.3d 1344, 1358 (Fed. Cir. 2017). "The court must: (1) determine the scope and

meaning of the patent claims asserted; and (2) compare the properly construed claims to the allegedly infringing device." *Id.* "With regard to the second step of the infringement analysis, the patentee must prove that the accused device embodies every limitation in the claim, either literally or by a substantial equivalent." *Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1573 (Fed. Cir. 1994).

"Literal infringement exists when every limitation recited in the claim is found in the accused device." *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1341 (Fed. Cir. 2016). In considering literal infringement at summary judgment, a court must resolve all inferences in favor of the patentee and may grant summary judgment against the patentee only if the court determines that no reasonable jury could find infringement. *Id.*

"While infringement under the doctrine of equivalents is a question of fact, '[w]here the evidence is such that no reasonable jury could determine two elements to be equivalent, district courts are obliged to grant partial or complete summary judgment.'" *Advanced Steel Recovery, LLC v. X-Body Equip., Inc.*, 808 F.3d 1313, 1319 (Fed. Cir. 2015) (alteration in original) (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997)). In making this determination, "the range of equivalents cannot be divorced from the scope of the claims." *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1382 (Fed. Cir. 2000) (per curiam). Indeed, "by defining the claim in a way that clearly exclude[s] certain subject matter," a patent may "implicitly disclaim[] the subject matter that was excluded and thereby bar[] the patentee from asserting infringement under the doctrine of equivalents." *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1346 (Fed. Cir. 2001) (alterations added).

BACKGROUND

Claim 1 of the '921 Patent states as follows, with the terms construed by the Court in bold:

> A method for determining whether a donated [human] mammary fluid was obtained from a specific subject, the method comprising:
>
> (a) testing a donated biological sample from the specific subject to obtain at least one reference identity marker profile for at least one marker;
>
> (b) testing a sample of the donated mammary fluid to obtain at least one identity marker profile for the at least one marker in step (a);
>
> (c) comparing the identity marker profiles, **wherein a match** between the identity marker profiles indicates that the mammary fluid was obtained from the specific subject; and
>
> (d) **processing** the donated mammary fluid whose identity marker has been matched with a reference identity marker profile, wherein the processed donated mammary fluid comprises a human protein constituent of 11-20 mg/mL; a human fat constituent of 35-55 mg/mL; and a human carbohydrate constituent of 70-120 mg/mL.

ECF 25-1 ('921 Patent).

The parties stipulated, and the Court adopted, that the term "wherein a match" means "a determination that the marker(s) in the biological sample and donated fluid or milk are the same and that there are no additional unmatched marker(s)." ECF 86 at 7-8. The Court construed the term "processing" to mean: "One or more of the following: filtering, heat-treating, separating into cream and skim, adding cream to the skim, or pasteurizing." *Id.* at 16. Claim 1 is representative, and the other asserted claims do not add anything substantive for purposes of the pending motion.[1]

[1] Although Ni-Q raised arguments related to the other asserted claims, Prolacta focused its arguments on the representative Claim 1.

The ’921 Patent claims testing and processing methods intended to standardize nutritional content in donated human mammary fluid and to ensure that the donor of a given sample is a match to a previously-identified donor. The inventors saw this as a solution to two different problems—human replacement milk that is nutritionally standardized (particularly important for preterm babies), and milk that is certifiably from a particular donor.

Regarding nutrition, the inventors established in the patent claims an acceptable range of protein, fat, and carbohydrates that the inventors believed was optimal for infants. Some naturally-occurring breast milk falls within these nutritional parameters. For milk that does not, the patent claims various processing steps, including filtering and adding cream, to alter the nutritional content to reach the standardized nutritional content. Regarding donor identification, the inventors established in the patent claims that a donor would provide a biological sample to obtain at least one reference identity marker. As described in the patent specification, this reference sample would come from methods known in the art, “such as, but not limited to, a cheek swab sample of cells, or a drawn blood sample, milk, saliva, hair roots, or other convenient tissue.” ’921 Patent, at 9:25-28. The reference identity marker nucleic acids would be isolated from “milk, saliva, buccal cells, hair roots, blood, and any other suitable cell or tissue” using methods known in the art such as “STR analysis of STR loci, HLA analysis of HLA loci or multiple gene analysis of individual genes/alleles.” *Id.* at 9:28-43. When mammary fluid is then donated and sent for processing, that mammary fluid would be tested against the reference identity marker to ensure a match, *i.e.*, that the same woman donated both the original reference marker and the mammary fluid.

DISCUSSION

A. Invalidity

Ni-Q argues that the asserted claims of the ’921 Patent (Claims 1, 2, 4, 6, 7, 8, 9, and 11) are invalid under 35 U.S.C. § 101 because the claims patent ineligible natural law with no inventive concept to transform the natural law into patent-eligible subject matter.

1. Step One Analysis

The first step under the Supreme Court’s framework in considering § 101 invalidity is to determine whether the asserted claims are directed to patent-ineligible subject matter, such as laws of nature, natural phenomena, and abstract ideas. *Alice*, 134 S. Ct. at 2355; *Mayo*, 566 U.S. at 70; *Vanda Pharms., Inc. v. West-Ward Pharms. Int’l Ltd.*, 887 F.3d 1117, 1133-34 (Fed. Cir. 2018). Because “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,” *Mayo*, 566 U.S. at 71, “it is not enough to merely identify a patent-ineligible concept underlying the claim; [the court] must determine whether that patent-ineligible concept is what the claim is ‘directed to.’” *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016).

Ni-Q argues that the presence of identity markers such as DNA and proteins in a woman’s tissue or milk is natural, and the nutritional levels required by the patent occur naturally, as alleged by Prolacta in its Answer and as found by the Court in its Opinion and Order on Claim Construction. In its briefing on the motion, Prolacta responds that the claims are directed to producing safer milk that is standardized with optimal nutritional values. Prolacta argues that the limitations in Claim 1(a) through 1(d) are directed to a novel method for selecting for processing safe milk from health-screened donors and Claim 1(d) is directed to manufacturing a nutrient-enhanced human milk product.

The Court agrees that the asserted claims are directed to the laws of nature. The presence of identity markers such as DNA in a woman's mammary fluid and other biological tissue is natural. Although the patent describes the human action of testing the original reference sample and the mammary fluid sample and comparing them, that does not convert the claim to patent-eligible subject matter. The relationship of the markers in the samples exists naturally. *See Mayo*, 566 U.S. at 77 ("While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law."). Claim 1 merely describes the natural law that two different biological samples from the same individual contain the same identity markers and thus can be tested and compared. *See Cleveland Clinic Found. v. True Health Diagnostics, LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017) ("Because the testing patents are based on the relationship between cardiovascular disease and heightened MPO levels that exists in principle apart from human action, they are directed to a patent-ineligible law of nature." (citation and alterations omitted)).

Prolacta's argument to the contrary is unpersuasive. The limitations of Claim 1(a) through 1(d) require no step, method, or process relating to safety or the health screening of donors. The limitations of the claim merely require testing a reference sample of a donor, testing a sample of the donated mammary fluid, comparing the two test results, and processing only the mammary fluid when the two tests match. Claim 1 thus ensures that mammary fluid is processed only when it is the same donor who gave both the reference sample and the mammary fluid. There is nothing in Claim 1, however, that requires testing the donor for disease or drug use or

anything else relating to health or safety. Indeed, the claim itself states that it is a "method for determining whether a donated mammary fluid was obtained from a specific subject." '921 Patent, at 21:46-47. The claim is about identification—it does not suggest that its goal or purpose relates to safety or health concerns.

Prolacta mainly relies on text from the specification to support its theory that Claim 1 is directed to safety and health screening. First, the Court notes that the primary focus in a § 101 analysis is the text of the claims. *See Mayo*, 566 U.S. at 77-78 (looking only to the text of the claims in invalidating the patent); *Vanda*, 887 F.3d at 1135 (focusing on the text of the claims at issue and how they differed from the claims at issue in *Mayo*, and considering the specification only for how it explained the significance of the limitation set out in the claims). It is the claims that must confine the reach of the patent, not the specification. *See, e.g.*, *Mayo*, 566 U.S. at 87 (noting, in invalidating claims, that "the patent claims do not confine their reach to particular applications of those [natural] laws"); *Genetic Techs. Ltd. v. Merial, L.L.D.*, 818 F.3d 1369, 1374-75 (Fed. Cir. 2016) (invalidating claim because it essentially covered all applications, even though the specification provided examples of applications to specific diseases).

Second, although the Court considers the claims in light of the specification, that only gets Prolacta so far. For example, if Claim 1 had stated a goal or purpose of safety or confirming health-screened donors, the Court could look to the specification for the means for achieving that goal in considering Ni-Q's § 101 challenge. *See Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1295 (Fed. Cir. 2016). Claim 1, however, does not include such a goal or purpose. The specification can also explain in more detail a limitation set forth in a claim. *Vanda*, 887 F.3d at 1135. The limitation of processing milk only by health-screened donors, argued by Prolacta, also is not contained within Claim 1.

Moreover, the specification is not specific enough to convert Claim 1 to a method for selecting safe milk from health-screened donors, even if the specification could limit the claim. The specification broadly states: "Testing donors to confirm their identity improves safety of donated milk." '921 Patent, at 9:1-2. It provides no further detail, other than the testing "ensures the provenance of the donated milk." *Id*. at 9:3. But that merely confirms the identity of the donor, not the health of the donor or safety of the milk. Later, in Example 1, the patent provides that a woman and her biological tissues and milk "will" undergo various steps, but that she "*can* also be screened (using the reference sample or another sample) for, *e.g*., drug use, viruses, bacteria, parasites, and fungi *etc*., to determine her health." *Id.* at 21:6-9 (emphasis added). Thus, the safety and health screening emphasized by Prolacta is optional even in the specification. It is, therefore, not a reasonable interpretation of Claim 1 that it is directed to a method for selecting safe milk from health-screened donors.

Prolacta's argument that Claim 1 covers a novel method of standardizing optimal nutrient level also is unavailing. As conceded by Prolacta, the nutrient levels set out in Claim 1(d) occur naturally in breast milk. *See* ECF 57 at 15 (Prolacta's First Am. Answer and Counterclaims at ¶¶ 22-24) (stating that it is "common for standard, unfortified human breast milk" to have the claimed nutrient ranges); ECF 25-4 at 2 (Declaration of Prolacta's Chief Executive Officer Scott A. Elster, ¶ 6) (same). In those circumstances, no nutrient enhancement is required. As the Court stated in its claim construction, when the donated mammary fluid naturally falls within the claimed nutrient ranges, the only processing that is required under Claim 1 is pasteurization. When the nutrient levels do not meet the claim's limitations, other processing steps may be

required, such as filtering or adding cream to skim. Claim 1, however, does not require those processing steps.[2]

Claim 1(d) does not require that nutrient levels of donated mammary fluid be altered. Nor does the text of the claim include anything about optimal nutrient levels. It merely requires that after processing is complete, the mammary fluid consist of wide-ranging levels of nutrients that, as conceded by Prolacta, are naturally found in human breast milk.

The Court provided the parties with a tentative Opinion and Order and gave them the opportunity to respond. In response, Prolacta shifted its argument at step one and now asserts that Claim 1 is directed to patent-eligible subject matter because it applies a natural phenomenon to select what milk to process. Prolacta argues that Claim 1 "produces a safer human milk product by excluding contaminated milk from processing regardless of whether known donors are health screened." Prolacta focuses on how excluding contamination from unscreened nonmatching donors creates a safer milk product. Prolacta's new argument is not persuasive.

[2] Prolacta contends that the Court's claim construction requires that Prolacta "cherry pick" and only process mammary fluid that naturally meets the nutritional limitations set out in Claim 1. That is an unreasonable interpretation of the Court's claim construction. The Court noted that the patent describes that most donated mammary fluid does not fall within the nutrient limitations, but the patent does not suggest that mammary fluid *always* falls outside the nutrient level requirements of Claim 1. The Court thus found that Claim 1 did not *necessarily* require altering the nutritional content or filtering the donated mammary fluid. It merely required that the nutritional levels be met after processing is complete. Thus, if donated mammary fluid naturally falls within the nutrient level limitations, the only processing step that would be required for that donated milk under the text of Claim 1 is pasteurization. The Court noted that the patent sets out five types of processing. The other types of processing are involved when the nutrient levels are not naturally met by the donated mammary fluid, and in some of the other claims of the patent. That is why the Court's construction of processing is: "One *or more* of the following: filtering, heat-treating, separating into cream and skim, adding cream to the skim, or pasteurizing." (emphasis added). If the Court's construction required processing only the mammary fluid that already met the nutrient level limitations, then the only processing step would be pasteurization and the "or more" steps of filtering, separating into cream and skim, and adding cream to skim would be superfluous.

As discussed above, Claim 1 merely ensures the provenance, or origin, of the donor. If the donor is not health screened, selecting to process mammary fluid from that donor (and excluding fluid from other donors) cannot produce a safer human milk product. If that donor has an infectious disease, repeatedly processing her milk because it matches her identity profile creates a less safe milk product. Moreover, excluding milk from others, which may come from someone who does not have an infectious disease, merely because it did not come from the original, unscreened donor, does not automatically make a safer milk product. The safety of the milk product is tied to health screening of the donor, which is not required by the patent.

Claim 1 is a broad claim that is not limited to a particular application of natural law. It is not limited to commercial human breast milk production, to certain processing that alter the makeup of the breast milk, or to testing breast milk donors for viruses, bacteria, drugs, or other health issues and then ensuring that later-donated milk matches the originally-screened donor. Indeed, it purports to cover any use where: (1) a donor has donated a reference sample and mammary fluid that are tested for a match; (2) if there is a match, the donated mammary fluid is processed using any of the five types of processing; and (3) after processing, the mammary fluid contains the identified nutrient ranges. Because these nutrient ranges are found naturally in breast milk, the claim's covered use could include, for example, researchers who are testing the efficacy of DNA comparisons between breast milk and other biological samples and in so doing heat-treat or pasteurize the milk.

Claim 1, therefore, is impermissibly directed to a patent-ineligible subject. *See, e.g.*, *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, --- F.3d ---, 2019 WL 453489, at *5-6 (Fed. Cir. Feb. 6, 2019) (finding claims failed at step one, even though they involved an "innovative laboratory technique" and "concrete steps," because they "recite a natural law and

conventional means for detecting it"); *Cleveland Clinic*, 859 F.3d at 1361 (invaliding claims that contained no treatment limitations and instead broadly covered "'seeing' MPO already present in a bodily sample and correlating that to cardiovascular disease"); *Genetic Techs*, 818 F.3d at 1374-75 (finding that claims were directed to a natural phenomenon because "Claim 1 covers any comparison, for any purpose, of any non-coding region sequence known to be linked with a coding region allele at a multi-allelic locus. . . . [A]lthough the specification does provide some examples of linked alleles known to be diagnostic of inherited diseases such as cystic fibrosis and muscular dystrophy[,] Claim 1 broadly covers essentially all applications, via standard experimental techniques, of the law of linkage disequilibrium to the problem of detecting coding sequences of DNA"); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015) (invalidating a patent claiming a method for detecting paternal DNA that naturally occurs in maternal serum because "the claimed method begins and ends with a naturally occurring phenomenon"). The other asserted claims challenged by Ni-Q do not add anything new or substantive that alter the Court's analysis. They are also directed to a patent-ineligible subject.

2. Step Two Analysis

The second step of the *Alice/Mayo* framework is to determine whether the claims contain an inventive concept sufficient to transform the claimed naturally-occurring phenomenon into a patent-eligible subject. The inventive concept must be "new and useful." *Ariosa*, 788 F.3d at 1377. "Simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." *Mayo*, 566 U.S. at 82. "To save a patent at step two, an inventive concept must be evident in the claims." *Cleveland Clinic*, 859 F.3d at 1362 (citation omitted); *see also Berkheimer v. HP, Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018) (noting that "improvements in the specification" must be "captured in the claims").

Ni-Q argues that Claim 1 contains no inventive concept sufficient to meet the *Alice/Mayo* step two requirements. Ni-Q asserts that Prolacta's comparison of DNA to match the reference sample to the donated mammary fluid was not new or inventive, and that this fact is admitted in the patent. Ni-Q also asserts that because processing can include mere pasteurization, that is not a new or innovative step. Ni-Q adds that none of the remaining asserted claims add anything new or inventive that render them patentable under step two.

Prolacta responds that three aspects of the claims are new or inventive: (1) applying DNA analysis to mammary fluid; (2) selecting mammary fluid for processing based on a matching processing that ensured the donated fluid was from a specific subject, thereby eliminating the risk of communicable diseases in donated milk; and (3) requiring the recited nutrient ranges. Prolacta asserts that these steps were not known in the prior art and they were not well understood, routine, or conventional. The latter two arguments by Prolacta are the same arguments Prolacta previously asserted in arguing Claim 1's validity at step one. They are rejected because, as discussed above, the elimination of health concerns and communicable diseases in processed milk is not contained in any of the asserted claims (and therefore cannot provide an inventive concept) and the required nutrient ranges may not require any processing other than pasteurization of donated milk, which is not new or inventive.

Prolacta's first argument, however, that applying DNA testing to mammary fluid was an inventive concept, is a new argument. Prolacta submits the declaration of Randolph Nagy, former Vice President of Sales and Marketing at Bode Technology, whom Prolacta engaged to perform the DNA matching. At that time, Bode had never extracted DNA from breast milk. After six months of refining its process, Bode met Prolacta's DNA matching requirements.

Bode also published an article about detecting through DNA analysis a minor contributor from mixed samples of human milk. At the time, Bode performed a literature search on the topic of isolating and extracting DNA from breast milk. Bode found two articles. One related to RNA extraction from epithelial cells in breast milk. The other was a feasibility study on isolating DNA in breast milk for epidemiologic studies of breast cancer. Nagy states in his declaration that using DNA in human milk to create a genetic link between human milk and a screened donor and to detect and exclude mixtures of milk containing DNA from unknown and unscreened donors was a completely new application in the field of DNA analysis. He notes that the two articles did not discuss using breast milk DNA in the manner developed by Prolacta.

One problem with Prolacta's argument and Nagy's declaration is that, as discussed above, nothing in the claims requires screening of the donor. Thus, the "completely new application" discussed by Nagy—the genetic link between screened donors and donated milk and excluding milk containing DNA from unknown and unscreened donors—is not the application in the claims. The claims merely require matching to identify that the donated mammary fluid is from a specific subject, regardless of whether that subject has been screened for health problems or drug use. Using DNA to match a person's identity is not a new or inventive use.

Another problem with Prolacta's argument and Nagy's declaration is that the '921 Patent defines identity marker and mammary fluid much more broadly than Nagy's discussion of breast milk and DNA. Mammary fluid is not just breast milk and colostrum, but also includes "solid fractions of the mammary fluid, whole cells or cellular constituents, proteins, glycoproteins, peptides, nucleotides (including DNA and RNA polynucleotides), and other like biochemical and molecular constituents of breast milk." '921 Patent, at 4:24-33. The patent defines "identity marker" as "a marker that can be used to identify an individual subject," including, but not

limited to, any "genes, alleles, loci, antigens, polypeptides, or peptides." *Id*. at 4:34-38. The claim term "identity marker profile" is defined to mean any profile of identity markers that can identify one human from 100,000, 1 million, or 5 million humans. *Id*. at 4:39-45. The claims thus do not require the matching be through maternal DNA or the process described by Nagy. Any identity marker will suffice.

Prolacta and Nagy's attempt to distinguish the two other articles relating to breast milk are not persuasive given the text of the claims. That one article involved RNA is not dispositive because mammary fluid is defined to include RNA polynucleotides. That the articles do not discuss using DNA to match donors screened for health problems to create a safe milk product is not relevant because the claims of the '921 Patent also do not require this use. Accordingly, the mere concept of finding DNA in mammary fluid was not new or inventive, and the new or inventive use as discussed by Nagy is not what is in the patent claims.

The '921 Patent acknowledges that obtaining identity markers was known in the art and that testing identity markers also was known in the art. Using such tests to match a subject's identity is not new or inventive. *See Athena*, 2019 WL 453489, at *8 (noting that "applying standard techniques in a standard way to observe a natural law does not provide an inventive concept"). Because that is all the claims cover, the claims add no new or inventive concept not already known in the art. Considering the steps "as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately." *Mayo*, 566 U.S. at 79.

Moreover, Prolacta's argument that applying DNA markers to mammary fluid was itself the inventive concept cannot support a finding at step two. "This is because '[t]he inventive concept necessary at step two . . . cannot be furnished by the unpatentable law of nature . . .

itself.'" *Athena*, 2019 WL 453489, at *8 (alterations in original) (quoting *Genetic Techs*, 818 F.3d at 1376)).

The claims cover laws of nature—identity markers that exist in a subject and mammary fluid with nutrient levels that occur in nature. The remaining steps (testing the identity markers for a match, pasteurization) "consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." *Mayo*, 566 U.S. at 79-80. The claims, thus, fail at step two.

B. Infringement

Ni-Q also asserts that it does not perform the "wherein a match" step of the '921 Patent and thus has not literally infringed the patent or infringed the patent under the doctrine of equivalents. The Federal Circuit has discussed the Rule 56 burden shifting in the context of a motion for summary judgment of noninfringement as follows:

> As the movant, Dow had "the initial responsibility of identifying the legal basis of its motion, and of pointing to those portions of the record that it believes demonstrates the absence of a genuine issue of material fact." *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001). Dow satisfied this burden by identifying that its accused process lacks a "pressurized collection vessel," as construed, and by pointing to record evidence suggesting that, in its process, "the material continuously passed through the heat exchangers." J.A. 914 ("Dow's dispersion is only collected at the very end of the Dow process in a large open-to-the-atmosphere plastic crate or an even larger, open-to-the-atmosphere storage tank, neither of which is pressurized."). Accordingly, "the burden shift[ed] to [Akzo] to designate specific facts showing that there is a genuine issue for trial." *Novartis*, 271 F.3d at 1046. The court correctly determined that Akzo failed to meet that burden.

Akzo Nobel Coatings, Inc. v. Dow Chem. Co., 811 F.3d 1334, 1341 (Fed. Cir. 2016) (alterations in original).

The parties stipulated to the definition of "wherein a match" as: "a determination that the marker(s) in the biological sample and donated fluid or milk are the same and that there are no additional unmatched marker(s)." Ni-Q argues that this definition encompasses two different steps and that it has never performed the second step, determining that there are no additional unmatched markers. Prolacta responds that determining that the reference sample and milk sample are the same necessarily requires a finding that there are no unmatched markers and that Ni-Q's laboratory does perform the test for unmatched markers and thus Ni-Q has infringed the patent.

The Court agrees that the definition stipulated to by the parties encompasses two separate determinations: (1) a determination that the marker in the reference sample and donated milk are the same; *and* (2) a determination that there are no additional unmatched markers. The definition connects the two clauses with the conjunction "and," which shows that both items are part of the "determination" that is encompassed in the definition. Indeed, this is precisely how Prolacta urged the Court to define the term before the parties stipulated to the definition. *See* ECF 43 at 15 ("Accordingly, the 'wherein a match' limitation should be construed to require (1) an affirmative determination that the markers in the biological sample and donated fluid or milk are the same *and* (2) that there are no additional unmatched markers." (emphasis in original)).

Genetics Associates performed Ni-Q's testing on its donated breast milk.[3] Ni-Q instructed Genetics Associates to: (1) identify identity marker profiles in buccal swab samples Ni-Q collected from its milk donors; (2) identify identity marker profiles in milk samples Ni-Q provided to Genetics Associates; (3) compare those profiles; and (4) advise Ni-Q whether the markers match. Ni-Q did not consider contamination and thus never instructed Genetics

[3] Ni-Q stopped testing donated breast milk in approximately July 2017.

Associates to test whether the milk samples contained unmatched markers. Ni-Q maintained the raw milk to be processed and the database linking the samples provided to Genetics Associates and the larger volume of raw milk. Ni-Q also processed the milk. Genetics Associates played no role in processing the milk.

In setting up its testing protocol, Genetics Associates validated both identity matching protocols and protocols for testing for contamination at a certain threshold. It discovered that its methods allowed it to detect contamination at levels above 20 percent. Genetics Associates' test could not discern contamination at levels below 20 percent. One method of determining contamination was from electropherograms revealing additional peaks beyond what one would expect from a single sample. Ni-Q did not receive those electropherograms, but Genetics Associates would review them to determine whether to retest a sample or whether a sample was not a match because of contamination.

Ni-Q argues that the '921 Patent requires *a determination that the milk processed* had no additional unmatched markers, and because Ni-Q processed the milk and did not make that determination before processing, Ni-Q did not infringe the patent. Therefore, argues Ni-Q, even if Genetics Associates' test provides results relating to unmatched markers for a representative sample of milk, that does not make Ni-Q's processing of milk infringing. Ni-Q provides as an example the one sample rejected by Genetics Associates for contamination—the sample was contaminated by another sample in shipping to Genetics Associates. Genetics Associates' test results related to the small sample it was provided, but Genetics Associates made no "determination" regarding unmatched markers relating to the gallons of milk sitting in Ni-Q's warehouse. Ni-Q also argues that Prolacta cannot rely on Genetics Associates' test to assert

infringement because Genetics Associates' test can only detect unmatched markers above 20 percent contamination.

Genetics Associates' inability to detect unmatched markers below 20 percent contamination renders its test non-infringing. The definition of "wherein a match" requires "no" unmatched markers. The test by Genetics Associates allows for unmatched markers up to 20 percent and, thus, does not meet the claim's requirements. Additionally, the claim definition requires a determination that the *milk processed* had no additional unmatched markers (not the *milk tested*). It is undisputed that Ni-Q made the determination regarding what milk to process. Ni-Q did not consider whether there were unmatched markers in making its determination regarding what milk to process.

Moreover, the fact that *Genetics Associates* makes some determination of unmatched markers does not automatically make *Ni-Q* liable for patent infringement. Prolacta cites *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015), for the proposition that the conduct of Genetics Associates can be attributable to Ni-Q for purposes of infringement. In *Akamai*, the Federal Circuit held:

> Where more than one actor is involved in practicing the steps, a court must determine whether the acts of one are attributable to the other such that a single entity is responsible for the infringement. We will hold an entity responsible for others' performance of method steps in two sets of circumstances: (1) where that entity directs or controls others' performance, and (2) where the actors form a joint enterprise.
>
> To determine if a single entity directs or controls the acts of another, we continue to consider general principles of vicarious liability. In the past, we have held that an actor is liable for infringement under § 271(a) if it acts through an agent (applying traditional agency principles) or contracts with another to perform one or more steps of a claimed method. We conclude, on the facts of this case, that liability under § 271(a) can also be found when an alleged infringer conditions participation in an activity or receipt of

> a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance.

Id. at 1022-23 (footnotes and citations omitted).

Prolacta argues that Ni-Q directs and controls Genetics Associates because it conducts testing under a contract with Ni-Q and under Ni-Q's direction and because Genetics Association accessed benefits by performing steps of the patented method identified by Ni-Q and under the terms prescribed by Ni-Q. The flaw in Prolacta's argument is that the undisputed evidence in the record is that Ni-Q did not direct Genetic Associates to test for unmatched markers, provide terms under which the milk should be tested for unmatched markers, or condition Genetic Associates' payment for testing on performing a test for unmatched markers. *See Medgraph, Inc. v. Medtronic, Inc.*, 843 F.3d 942, 948 (Fed. Cir. 2016) (affirming summary judgment of noninfringement when "the evidence presented to the district court indisputably shows that Medtronic does not condition the use of, or receipt of a benefit from, the CareLink System on the performance of all of Medgraph's method steps"). Ni-Q, therefore, has not literally infringed the '921 Patent.

It also does not appear that Prolacta is asserting infringement through the doctrine of equivalents. Prolacta did not respond to this portion of Ni-Q's motion. Even if Prolacta is making such an assertion, Ni-Q also did not infringe the '921 Patent under the doctrine of equivalents. This type of infringement requires a finding "that the accused product or method performs the substantially same function in substantially the same way with substantially the same result as each claim limitation of the patented product or method." *AquaTex Indus., Inc. v. Techniche Sols.*, 479 F.3d 1320, 1326 (Fed. Cir. 2007). "A patentee must establish 'equivalency on a limitation-by-limitation basis' by 'particularized testimony and linking argument' as to the insubstantiality of the differences between the claimed invention and the accused device or

process." *Akzo*, 811 F.3d at 1342 (quoting *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1566 (Fed. Cir. 1996).

The purpose of the second step of the "wherein a match" requirement—making sure there are "no unmatched markers"—is to prevent contamination from unscreened donors. '921 Patent, at 2:3-9; 10:21-30; ECF 99 at 4 (Declaration of Martin L. Lee, ¶ 10). Ni-Q does nothing equivalent to that step to prevent contamination from other donors. Summary judgment in favor of Ni-Q, is, therefore, appropriate.

CONCLUSION

Plaintiff Ni-Q, LLC's Motion for Summary Judgment (ECF 88) is GRANTED. The Court finds that there are no genuine issues of material fact, the asserted claims of the '921 Patent are invalid under 35 U.S.C. § 101, and Plaintiff has not infringed the asserted claims of the '921 Patent even if they were valid.

IT IS SO ORDERED.

DATED this 13th day of February, 2019.

/s/ *Michael H. Simon*
Michael H. Simon
United States District Judge